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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/745,095	12/20/00	APPEL	L PC10818AJTJ

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EXAMINER	
GOLLAMUDI,S	
ART UNIT	PAPER NUMBER
1616	5

DATE MAILED:
10/29/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application N .	Applicant(s)	
	09/745,095	APPEL ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE f this c mmunication appears n the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-131* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-131* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 7-11, 17-32, 40-43, 46-48, 52-55, 57-81, 88-97, 101, 103-108, 118-123, and 130-131, drawn to controlled dosage form, classified in class 424, subclass 472.

II. Claims 2, 7-9, 12-32, 44-45, 49-53, 56-81, 88-97, 101, 103-108, 118-122, 124, and 130-131, drawn to a controlled dosage form, classified in class 424, subclass 472.

III. Claims 3, 7-9, 12-32, 40-43, 46-48, 52-66, 74-81, 88-97, 103-108, 118-122, 125, and 130-131, drawn to a controlled dosage form, classified in class 424, subclass 472.

IV. Claims 4, 7-9, 12-32, 40-43, 46-48, 52-55, 57-87, 98-112, 118-122, 126, and 130-131, drawn to a controlled dosage form, classified in class 424, subclass 473.

V. Claims 5, 7-9, 12-24, 33-43, 46-48, 54-55, 57-81, 95-97, 101, 103-108, 118-112, 127, and 130-131, drawn to a controlled dosage form, classified in class 424, subclass 472.

VI. Claims 6, 7-9, 12-16, 22-24, 40-43, 46-48, 52-55, 57-81, 95-97, 101, 103-108, 118-122, 128, and 130-131, drawn to a controlled dosage form, classified in class 424, subclass 472.

VII. Claims 113-117, and 129, drawn to a controlled dosage form, classified in class 424, subclass 472.

The inventions are distinct, each from the other because:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different controlled dosage forms have different properties and effects. Invention II contains a tableting aid which Invention I does not, thus changing the properties, such as compressibility, of the dosage form.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different controlled dosage forms have different properties and effects. Invention III and Invention I are different coating properties of Invention III, Invention II having rapid onset.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different controlled dosage forms have different properties and effects. Invention IV contains a cellulosic polymer which Invention I does not, thus changing the viscosity and release rate of Invention IV. Further, Invention V has a porous layer changes the properties of the dosage form.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different controlled dosage forms have different properties and effects. Invention V contains a fluidizing agent which Invention I does not, thus the agent increases the fluidity of the composition and increases the rapid onset of the drug, through the mechanization of decreasing the pressure of extruding the drug out of the port.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different controlled dosage forms have different properties and effects. Invention VI contains a solubilizer which Invention I does not, thus increasing the solubility of insoluble drugs.

Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different controlled dosage forms have different properties and effects. Invention VII contains is in an amorphous dispersion whereas Invention I is not.

Inventions II and III, IV, V, VI, and VII respectively are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §

806.04, MPEP § 808.01). In the instant case the different controlled dosage forms have different properties and effects. Invention II contains a tableting aid changing its compressibility which Inventions, III, IV, V, VI, and VII respectively, do not.

Inventions III and IV, V, VI, and VII respectively, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different controlled dosage forms have different properties and effects. Invention III contains a different coating which changes the onset of Invention III compared to Inventions IV, V, VI, and VII respectively.

Inventions IV and V, VI, and VII respectively, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions controlled dosage forms have different properties and effects. Invention IV has a porous layer which changes its properties compared to Inventions V, VI, and VII respectively.

Inventions V and VI and VII respectively, are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions controlled dosage forms have different properties and effects. Invention V contains a fluidizing agent, which changes its properties as set forth above, and thus its effect is different than Inventions VI and VII respectively.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions controlled dosage forms have different properties and effects. Invention VII composition is in an amorphous dispersion, changing its properties. Further, Invention VI contains a solubilizer, which Invention VII does not, thus both dosage forms have different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: different dosage forms with different and distinct agents.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, drug, swelling agent, drug-entraining agent, tableting aid, cellulosic polymer, fluidizing agent, solubilizer, pore former, and concentration enhancing agent are generic in each dosage form.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Mr. Jones on October 22, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

JOSE' G. DEES
SUPERVISORY PATENT EXAMINER
1616

SSG